



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/730,476

12/08/2003

Chunying Du

65015

3329

27148 7590 04/11/2007
POL SINELLI SHALTON FLANIGAN SUELTHAUS PC
700 W. 47TH STREET
SUITE 1000
KANSAS CITY, MO 64112-1802

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

04/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/730,476

Applicant(s)

DU ET AL.

Examiner

Hope A. Robinson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/5/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22, 23, 26, 30-32, 38-42, 49-70 and 72-96 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 22, 23, 26, 30-32, 38-42, 49-70, 72-86 and 88-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Applicant's election without traverse of Group II (claims 1-19, 22-23, 30-32, 38-42 and 49-50 and 71; SEQ ID NO:45) on October 5, 2006, is acknowledged.

Claim Disposition

2. Claims 1-19, 22-23, 26, 30-32, 38-42, 49-70, 72-96 are pending. Claims 17-19 and 87 are under examination. Claims 1-16, 22-23, 26, 30-32, 38-42, 49-70, 72-86 and 88-96 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. The claims are only being examined to the extent that they pertain to the elected invention, SEQ ID NO:45.

Specification

3. The specification is objected to because of the following informalities:

*The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as SEPHAROSE™, for example, has been noted in this application (see page 61). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks

Art Unit: 1652

should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. Applicant is urged to review the entire specification for other occurrences and amend the specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "Polypeptides, Compositions and Methods for cleaving IAP".

The Brief Description of the Drawings are objected to because Figures 1, 2, 3, 4, 5 and 6 are described, however, the Figures depict for example Fig. 1A or Fig 2A. It is suggested that the specification is amended to recite for example, "Figures (1A-E) relates to Omi cleavage of IAP...".

The sequence notation throughout the specification is improper, see for example page 16, "SEQ ID NO.44" which should be "SEQ ID NO:44".

Correction is required.

Sequence Compliance Objection

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:".

Art Unit: 1652

The specification discloses sequences that have not been identified by a sequence identifier, see for example, page 14: Fig. 5B "ASQRLFPG" for example and "AVPS"; and page 15: Fig. 7C "DEV D", (and throughout the specification). If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

In addition, the sequence statement, affirms that the content of the sequence listing information in the CRF is identical to the paper copy of the sequence listing, however, does not indicate that, where applicable, "includes no new matter". Therefore, the instant application fails to fully comply with the sequence rules. A signed statement regarding no new matter is required.

Drawing

5. The drawings filed on December 8, 2003 are accepted by the examiner.

Claim Objection

6. Claim 17 is objected to because of the following informalities:

Art Unit: 1652

Claim 17 is objected to because the claim recites non-elected subject matter. In addition, the claim is objected to for the recitation of the acronym "IAP" without the spelled out meaning.

Correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

7. Claims 17-19 and 87 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 17 and the dependent claims hereto are drawn to a polypeptide, which reads on a product of nature. Note that claim 19 reads on humans with the phrase "expressed intracellular". The claims should be amended to indicate the hand of the inventor, for example the insertion of "isolated" or "purified" in connection with the protein to identify a product not found in nature (see MPEP 2105).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 17-19 and 87 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 18 is indefinite for the recitation of "the polypeptide of claim 17" because claim 17 comprises several polypeptides and the language in the claim in singular. It is unclear which of the polypeptides represented in claim 17 is intended in claim 18. In addition, the claim is indefinite for the recitation of "a pharmacologically acceptable carrier" because claim 17 is directed to a compound not a composition. No clear antecedent basis between the two claims.

Claims 2-4 are indefinite because the claims recite positions and mutations, however, no reference structure is provided. For example it is unclear what sequence has position S53N (claim 3). In addition, claims 2-4 are indefinite because the claims recite positions not found in SEQ ID NO:11. Note that SEQ ID NO:11 has been constructively been elected and the protein only has 38 residues, yet these claims recite positions such as "K62D".

Claim 17 is indefinite for the recitation of "Figure 1" because this renders the claim as incomplete since the limitations of the specification cannot be read into the claims. In addition, the positions found in the figure do not appear in the elected SEQ ID NO:11.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Smithkline Beecham PLC (EP828003 A2, March 11, 1998).

The reference teaches a protein structure that is 99.9% identical to the claimed SEQ ID NO:45 (variant Omi), see the alignment. Therefore, the limitations of the claims are met by the reference.

Conclusion

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

HOPE ROBINSON
PRIMARY EXAMINER